

**Assessing the tolerability of suprascapular and median nerve blocks for the treatment of
shoulder-hand syndrome - a feasibility study**

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INTRODUCTION

Background and Rationale

Chronic regional pain syndrome (CRPS) is a debilitating, painful condition characterized by severe pain of the shoulder and hand. It may occur in multiple settings, including post-trauma, post-surgery, or in the hemiparetic upper limb following a stroke. When this occurs in stroke patients, it is also referred to as shoulder-hand syndrome (SHS). In SHS, the stroke-affected upper extremity shows pathologic alterations including vasomotor (changes in temperature and skin colour); sudomotor (sweating and edema); motor signs/symptoms (weakness and tremor); trophic alterations of nails, hair, skin as well as joint contractures (Harden 2013). SHS is highly prevalent in the stroke population, affecting as many as 25% of these patients in Canada (Tepperman 1984). Due to its progressive nature, SHS frequently leads to severe functional impairment and chronic morbidity. Thus, SHS has a significant impact on stroke recovery, patients' ability to regain independence, and community reintegration (Kang 2012).

The pathophysiology of SHS is poorly understood. The two most commonly accepted mechanisms include neurogenic inflammation and/or autonomic nervous system dysfunction (Bussa 2015). Neurogenic inflammation may occur secondary to increased pro-inflammatory cytokines in the blood plasma and cerebral spinal fluid (Bussa 2013 and Taha 2007), and is supported by effective treatment with corticosteroids (Braus 1994; Kalita 2006; Rah 2012). The putative autonomic nervous system dysfunction mechanism is based upon the observation that there is an increased sensitivity of blood vessels to catecholamines and adrenergic sensitivity by nociceptive neurons (Bussa 2013), as assessed during sympathetic nerve blockade (Meier 2009; Carroll 2009; Aydemir 2006).

Due to the variability in how SHS presents itself, its clinical diagnosis can be challenging (Harden 2007). In order to address this challenge, a collaborative international task force has developed a set of validated diagnostic criteria, known as the Budapest criteria, which incorporates symptoms and signs of vasomotor, sudomotor, motor and trophic changes (Harden 2007 and 2013; see Appendix A). While the Budapest criteria have been validated in non-stroke populations (CRPS types 1 and 2), an important limitation is the lack of information regarding their reproducibility among users and within the stroke patient population. The sensitivity and specificity of the Budapest criteria in non-stroke populations has been reported to be 0.85 and 0.69, respectively (Harden 2013). To our knowledge, the inter-rater agreement of the Budapest criteria is unknown in the stroke population suffering from SHS.

Due to the lack of knowledge regarding the pathophysiology of SHS, treatment options vary, focusing on both pharmacologic and non-pharmacologic treatments for neuropathic-type pain (Cacchio 2009; Kalita 2006). One of the most widely accepted treatments for SHS is the administration of a high-dose pulse of corticosteroids, followed by a rapid taper. Three studies

have assessed this treatment approach and all have shown that pain is significantly reduced (Braus 1994; Kalita 2006; Rah 2012). Appendix B summarizes pharmacological, non-pharmacological (physical therapy and mirror therapy) and procedural interventions (sympathetic stellate ganglion block). Despite multiple treatment options, SHS often remains refractory and severely disabling.

Within the last decade, there has been exciting research in the field of peripheral nerve blockade for stroke patients with upper extremity pain. Jeon et al. (2014) evaluated 30 patients with hemiplegic shoulder pain (HSP) randomized to either intraarticular steroid injection, suprascapular nerve block (SSNB), or combined therapy. They showed a significant decrease in pain using the visual analog scale in all three groups at 1 hour, 1 week, and 1 month post-injection ($p=0.000$). Adey-wakeling et al. (2013) equally randomized 64 patients with HSP to SSNB or placebo injection. There was a significant difference in visual analog scale pain reduction (18mm) in the experimental group compared to placebo group at 1 week, 4 weeks, and 12 weeks ($p=0.02$) post-injection. Yasar et al. (2011) randomized 26 patients with HSP to two groups (intraarticular steroid injection and SSNB). There was significant reduction in VAS pain at 1 hour, 1 week, and 1 month post-injection ($p<0.001$) (see Appendix C for more details).

While these studies show promise for the management of generalized hemiplegic shoulder pain in the stroke population, to our knowledge, there has yet to be any study specifically evaluating the effect of peripheral nerve injection for the treatment of SHS. As SHS is a highly painful condition that often presents with allodynia and hyperalgesia of the hand and shoulder (Harden 2013), the tolerability of an injection in or near these regions may preclude their use in this particular population. There is therefore a need to ensure the tolerability of such treatments prior to evaluating their efficacy in patients with SHS. Based on the pain distribution of SHS, we have specifically chosen to evaluate the combined tolerability of two well-described peripheral nerve blocks: suprascapular and median nerve blockades, both of which have been deemed safe and effective in other settings (Jeon 2014; Adey-wakeling 2013; Yasar 2011; Liebmann et al 2006).

In order to evaluate the reproducibility of the Budapest criteria for SHS, we will measure the inter-rater agreement between 2 clinical assessors. Our preliminary findings would reassure investigators and funding agencies regarding the feasibility of conducting a larger clinical study.

OBJECTIVES

For this preliminary study, we have developed 2 independent Objectives:

Objective 1: Tolerability of Suprascapular and Median Nerve Blockade

We will evaluate the tolerability of ultrasound-guided suprascapular and median nerve blocks in stroke patients with SHS as determined using the Budapest criteria. Since tolerability is a subjective measure, it will be defined by a composite outcome including: a) Pain score prior to, during, and immediately following the procedure as measured by the visual analog scale (VAS); b) the rate of serious adverse events associated with this procedure; and c) the level of patient acceptance and satisfaction as determined by a validated post-procedure survey.

Hypothesis 1: Ultrasound-guided peripheral nerve blocks of the suprascapular and median nerves will be well tolerated by stroke patients with SHS.

Objective 2: Inter-rater Agreement of Budapest Criteria

We will assess the reproducibility of the Budapest clinical criteria for newly suspected cases of SHS. This will be achieved by estimating the level of inter-rater agreement between a resident and a staff physician working in stroke rehabilitation. We will therefore determine if there is variability in the clinical diagnosis among physicians with different levels of expertise.

Hypothesis 2: There is good to excellent inter-rater reliability (>0.60) of the Budapest clinical criteria between these two assessors.

MATERIALS AND METHODOLOGY

1) Population

Stroke patients with suspected shoulder-hand-syndrome (SHS) are most often identified on the inpatient stroke rehabilitation ward at Élisabeth Bruyère Hospital (EBH) or Saint Vincent's Hospital (SVH) in Ottawa, ON. They are occasionally encountered in the outpatient stroke clinics at EBH. Patients with suspected SHS will be referred to Dr. Campbell (a physical medicine and rehabilitation physician who specializes in stroke rehabilitation) for evaluation. This has been discussed with the other physicians at EBH and SVH. Such patients most commonly present with a painful shoulder and painful edematous hand. Subjects will be recruited over a 12-month period from the inpatient stroke rehabilitation unit at EBH, the restorative care inpatient program at SVH, and the stroke outpatient clinic at EBH.

Inclusion criteria: Subjects are required to be 18 years of age or older and have a presumptive diagnosis of SHS post-stroke with a minimum visual analog scale of 40mm (greater than 40mm is considered moderate pain).

Exclusion criteria: Subjects will be excluded from the study if they have significant cognitive impairment (mini-mental state examination <23) and language deficits (difficulty cooperating due to aphasia) as this may affect their response to the outcome measures. Subjects with uncontrolled hypertension ($>180/110$), septicemia, and brachial plexus injuries will be excluded. Patients who are blind and deaf will also be excluded, as they will be unable to adequately complete the post-procedure survey and VAS. Patients on anticoagulation medications will also be excluded on a case-by-case basis and medications will be held prior to injection if required for safety. Patients with INR >1.5 will be excluded.

2) Research procedures and instrumentation:

a) Suprascapular and median nerve blocking procedure

As part of their standard of care, all participants will receive their usual treatment for SHS as per Dr. Campbell's discretion. Patients receiving corticosteroids usually receive a

standardized regimen of prednisone 60mg daily from day 1 to 10 then a taper of 10mg daily, total treatment regimen is 15 days. While we will try to standardize this part of the treatment, it is possible that some patients may require a different treatment course, based on their response to therapy. Such patients will receive appropriate adjustments to care based on their clinical picture. Each participant will undergo an ultrasound-guided injection of the suprascapular nerve and median nerve by a trained radiologist or radiology fellow (under the supervision of the staff radiologist) at The Ottawa Hospital, General Campus. This will involve a subcutaneous injection of 1% lidocaine for local analgesia at each location followed by 1mL of 0.5% bupivacaine and 40mg of triamcinolone.

b) Ultrasound-guided nerve block technique:

Median nerve block: probe will initially be centered over the volar wrist and the median nerve will be identified. The nerve has a typical honeycomb appearance and the probe will be moved proximally to the midforearm between the flexor digitorum superficialis and the flexor digitorum profundus at the midline of the forearm (Liebmann et al 2006). The identified nerve will then be injected.

Suprascapular nerve block: is identified as a round hyperechoic structure at 4cm depth beneath the transverse scapular ligament in the scapular notch (Harmon and Hearty 2007). The identified nerve will then be injected.

c) Assessment of pain pre- and post-procedure with the visual analog scale.

The visual analog scale (VAS) is a subjective measure of pain on a scale of 0-100mm. The subjects will be supervised during the completion of VAS to minimized errors. The test-retest reliability of VAS has been shown to be good in literates ($r = 0.94$, $p < 0.001$) and in illiterates ($r = 0.71$, $p < 0.001$) (Hawker et al 2011). The VAS will be completed just prior to the procedure (scheduled for early morning), during the procedure, within 1 hour post-procedure, and 2 weeks post- procedure.

d) Detection of adverse events.

The radiologist performing the procedure will report the immediate adverse events on the physician's post-procedural survey (Appendix E). The participant will keep a logbook that will be returned 2 weeks post-procedure where they will list any adverse events. Each participant will receive a pamphlet with instruction on how to identify these adverse events and how to record them. Adverse events that have been associated with peripheral nerve blocks include:

- Increased pain during the procedure: the percentage of this is unknown in patients with SHS. Because of the high sensitivity to pain this may be increased.
- Nerve injury (8-10%): symptoms of nerve injury include pain, tingling and paresthesia. This can also include motor and sensory deficits. This is a temporary effect with only about 1 in 200 people having symptoms 6 months after the procedure.

- Hematoma: this is rare because a small gauge needle (22G or 25G) will be used as well direct pressure will be applied at the needle site following the procedures.
- Local anesthetic systemic toxicity (LAST): accidental intravascular injection of local anesthetic. The clinical manifestations of LAST include mild symptoms (ringing in ears, tingling in lips, and agitation) to severe neurological (seizures) and cardiovascular signs (hypertension, hypotension, tachycardia, bradycardia, ventricular arrhythmia, cardiac arrest). This complication is very rare as precautions are taken during the procedure to avoid inadvertent intravascular injection.
- Allergic reaction: this can be an allergic contact dermatitis or urticarial and anaphylaxis. Patient's known to have allergies to local anesthetics will be given a substitute medication.
- Infection: risk is negligible from a single-shot peripheral nerve block.
- Secondary injury: reduced sensation after nerve block puts subjects at risk of tissue injury.

e) Evaluation of the patient's acceptance and satisfaction

We will use an adapted post-procedure assessment questionnaire. The original questionnaire was used in a total of 566 patients for the purpose of determining the quality of multiple interventional pain management procedure (Zhou et al 2006). The questionnaire, as described by Zhou et al, includes 12 questions (7 Likert-type questions, 4 yes/no questions, and 1 open question). For our study, we have adapted this to 9 questions (2 Likert-type questions, 5 visual analog scales, and 2 yes/no questions) relevant to our study. Our adapted questionnaire will address the patients' overall satisfaction, pain, and comfort with the procedure. Four of the questions in the questionnaire will address satisfaction with the procedure. A participant is considered to be satisfied with the procedure if they did not have any undesirable reactions, were comfortable during the procedure, and would be willing to undergo the procedure again.

f) Overall calculation of tolerability

A composite score that will be determined by a) Pain score prior to and immediately following the procedure as measured by the VAS; b) the rate of serious adverse events associated with this procedure; and c) the level of patient acceptance and satisfaction as determined by a validated post-procedure survey. The levels of tolerability will be categorized as well tolerated, tolerated, and not tolerated. They are defined as the following:

- i. Well tolerated: either pain did not increase more than 18mm on the VAS during or post-procedure, participants had no serious adverse events, and participants are satisfied with the procedure.
- ii. Tolerated: No adverse events and one of: pain did not increase more than 18mm on the VAS either during or post-procedure OR participants are satisfied with the procedure
- iii. Not tolerated: Any adverse event OR patients experienced an increase of more than 18mm on the VAS either during or post-procedure AND participants are not satisfied with the procedure

g) Reliability of the Budapest Criteria

Two independent physicians will apply the Budapest clinical criteria to confirm or rule out the diagnosis of SHS. The two physicians will differ in their level of training with the training resident being a comparator to the stroke rehabilitation attending physician. Each assessment will be done independently and within 24 hours of each other to avoid changes in their clinical status. The physicians will not discuss their findings with the patient or each other (double blind) as this may lead the second independent assessor to make a similar conclusion. The attending physician independently of the second assessor will have the final decision on patient management in order to avoid alterations in standard of care. The evaluations by both the resident and attending physician will remain in a sealed opaque envelope in a locked drawer managed by our research assistant at EBH until the completion of the study. The evaluation forms will carry only the participants study number, and will carry no identifying data. Identifying data linked to the study number will be kept in a separate, encrypted electronic document on the Ottawa Hospital Server. Statistical assessment will be performed with the help of the Ottawa Methods Centre.

ENROLLMENT PROCEDURE AND SEQUENCE OF ASSESSMENT.

Enrolment for the study and sequence of assessment will be as follow for each participant:

- a) Referral:** Stroke patients with suspected shoulder-hand-syndrome (SHS) are most often identified on the inpatient stroke rehabilitation ward at Élisabeth Bruyère Hospital (EBH) or Saint Vincent's Hospital (SVH) in Ottawa, ON. They are occasionally encountered in the outpatient stroke clinics at EBH. Patients with suspected SHS will be referred to Dr. Campbell (a physical medicine and rehabilitation physician who specializes in stroke rehabilitation) for evaluation. This has been discussed with the other physicians at EBH or SVH. Such patients most commonly present with a painful shoulder followed by a painful edematous hand. Subjects will be recruited over a 12-month period from the inpatient stroke rehabilitation unit at EBH, the restorative care inpatient program at SVH, and the stroke outpatient clinic at EBH.
- b) Screening:** Two independent physicians will assess the patient using the Budapest clinical criteria. The diagnosis will be placed in a sealed envelope in a locked drawer until completion of the study.
- c) Recruitment:** the physical medicine and rehabilitation physician will then independently decide on patient management and recruitment for peripheral nerve blockade.
- d) Baseline pain:** this will be assessed when the participant is enrolled in the study.
- e) Intervention:** participants will have the ultrasound guided suprascapular and median nerve block within 1 week of diagnosis and recruitment.
- f) Post-procedure survey:** will be completed by both the participant and interventional radiologist within 1 hour following the procedure. This will include the VAS.
- g) Logbook:** a logbook will be given to each participant with an information pamphlet regarding the adverse events to monitor for. The participant will record any adverse events over a 2 week period.

- h) **2-week follow up:** participants will return their logbooks. They will also complete a final VAS.

OUTCOME MEASURES

Objective 1 (Primary outcome):

Patient tolerability. This will be defined by a composite score determined by: a) the difference between the level of pain from before (baseline), during, and 1 hour after the procedure as determined by the visual analog scale; b) the rate of serious adverse events associated with the procedure; and c) the level of patient acceptance/satisfaction as indicated by a validated post-procedural survey.

A lack of increase of pain of >18mm in the self-assessment test comparing before, during and after the procedure will indicate the patient tolerated the procedure. Additionally, absence of serious adverse events and participants' satisfaction with the procedure.

Objective 2 (Secondary outcomes):

Examiner's reliability of the Budapest clinical criteria. This will be achieved by estimating the level of inter-rater agreement through the intra-class correlation coefficient (ICC) and the limits of agreement. We expect a good to excellent inter-rater agreement with an ICC of greater than 0.60 (Cicchetti 1994).

Change in pain. The visual analog scale, similar to that in the questionnaire, will be used to address the change in pain from baseline (before procedure) to 2 weeks after the procedure.

STATISTICAL ANALYSIS

All statistics will be performed with the assistance of the Ottawa Methods Centre (Dr. Rosendo Rodriguez, who assisted us with the development of our protocol). Descriptive statistics and plots will characterize the distribution of pain scores obtained at baseline and after the procedure for all patients. Rates, proportions and ratios will describe the distribution of patients below and above the pre-determined cut-off. The cut-off is at least two of the three parameters: lack of increase of pain of >18mm post-procedure, no serious adverse events, and the patient was satisfied or very satisfied with the procedure. We will use t-tests to assess the significance of the differences in pain scores between baseline and each post-procedural examination. In case of substantial skewing of the data, suitable transformations or non-parametric alternatives will be considered (ie. Mann-Whitney U test).

Reliability of the Budapest criteria on the diagnosis of SHS will be assessed by intra-class correlations or kappa statistics and limits of agreement (95% confidence interval) (Rosner and Willet 1998). Bland-Altman's plots will display the differences in scores between physicians by incorporating their mean values (Bland and Altman 1986).

Sample size estimation. Based on our institution's history of new SHS patients, we estimate a rate of 1 to 2 per month, 10% of whom will be limited due to cognition and language impairment, we expect to have an average of 12 potentially eligible patients. Since roughly 2/3

of those are assumed to consent to the procedure, at least 8 to 10 participants are expected to enrol in a single year for this study.

ETHICAL ISSUES

All participants will receive the standard of care for SHS and will be treated by Dr. Campbell. Additional risks may occur with the addition of peripheral nerve blockade to the suprascapular and median nerves, as it is an interventional procedure. Informing the patients of the risks and providing them with a pamphlet on how to identify adverse events will mitigate these risks. Additionally, we will provide a contact number for the participants if they have any questions regarding symptoms.

FUTURE PLANS

This preliminary study addresses a novel treatment for stroke patients with SHS. It will provide information on the safety and tolerability of the proposed procedures. The information from this study will inform investigators that suprascapular and median nerve blockade is tolerable to stroke patients with SHS. One of our secondary outcomes, pain 2 weeks post-procedure, will also be informative regarding the short-term efficacy in alleviating pain with this treatment. We hope to use the data gathered from this study to design a larger study that will address the efficacy of this treatment for relieving pain.

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Appendix A

Budapest criteria for shoulder hand syndrome (Clinical criteria):

1. Continuing pain, which is disproportionate to any inciting event
 2. Must report at least one symptom in *three of the four* following categories:
 - a. Sensory: Reports of hyperalgesia and/or allodynia
 - b. Vasomotor: Reports of temperature asymmetry and/or skin color changes and/or skin color asymmetry
 - c. Sudomotor/Edema: Reports of edema and/or sweating changes and/or sweating asymmetry
 - d. Motor/Trophic: Reports of decreased range of motion and/or motor dysfunction (weakness, tremor, dystonia) and/or trophic changes (hair, nail, skin)
 3. Must display at least one sign **at time of evaluation** in *two or more* of the following categories:
 - a. Sensory: Evidence of hyperalgesia (to pinprick) and/or allodynia (to light touch and/or deep somatic pressure and/or joint movement)
 - b. Vasomotor: Evidence of temperature asymmetry and/or skin color changes and/or asymmetry
 - c. Sudomotor/Edema: Evidence of edema and/or sweating changes and/or sweating asymmetry
 - d. Motor/Trophic: Evidence of decreased range of motion and/or motor dysfunction (weakness, tremor, dystonia) and/or trophic changes (hair, nail, skin)
 4. There is no other diagnosis that better explains the signs and symptoms
- (Adopted from Harden 2013)

Appendix B

| Study | Methods | Results |
|-------|---------|---------|
|-------|---------|---------|

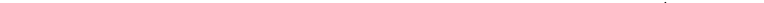
| | | |
|---|--|--|
| Non-pharmacological | | |
| Kondo et al. 2001 | 152 stroke patients admitted to a rehabilitation unit and followed for 200 days were monitored for the development of SHS. Half of the patients were treated with a physical therapy protocol to prevent SHS. The remaining patients received standard inpatient rehabilitation. | Incidences of SHS were 15/81 (18.5%) for patients receiving the protocol and 23/71 (32.4%) among patients who did not. |
| Cacchio et al. 2009 | 48 patients with SHS were all treated with convention PT and randomized into mirror therapy group. | There was significant improvement in pain and function ($p<0.001$) in the mirror therapy group. |
| Pharmacological - Corticosteroids | | |
| Braus et al. 1994 | 36 patients with SHS were randomized to receive methylprednisolone 8mg orally or placebo for 4 weeks. | No improvement was noted in placebo group after 4 weeks therefore switched to treatment group. Those receiving corticosteroids significant improvement in SHS that was maintained at 6 months. |
| Kalita et al. 2006 | 60 patients with SHS were randomized to receive prednisolone 40mg orally or piroxicam 20mg daily. | 83.3% of the prednisolone group had a significant improvement compared to 16.7% of the piroxicam group. |
| Rah et al. 2012 | 58 patients with SHS were randomized to receive triamcinolone 40mg orally or lidocaine placebo group. Pain level was assessed at 2, 4 and 8 weeks post treatment. | Significant improvement with VAS in treatment group compared to placebo group at 4 and 8 weeks ($p<0.05$). |
| Interventional - Sympathetic Ganglion Nerve Block | | |
| Price 1998 | Compared 7 patients with CRPS with stellate ganglion (n=4, 15ml lidocaine 1%) or lumbar sympathetic block (n=3, 10ml bupivacaine 0.125%) with normal saline. | No significant difference |
| Aydemir 2006 | Compared stellate ganglion lidocaine block (10 ml of 1%) plus sham stellate ganglion ultrasound | No significant difference |

| | | |
|----------------|---|---|
| | block (n = 9) to stellate ganglion ultrasound 'block' (consisting of ultrasound delivered non-invasively over the stellate ganglion) plus sham stellate ganglion lidocaine block (10 ml of saline; n = 9). | |
| Carroll 2009 | Compared 9 patients with CRPS (7 completed study) with sympathetic block with botulinum toxin A (75 units) plus bupivacaine (10 ml of 0.5%) with just bupivacaine (10 ml of 0.5%) in people with complex regional pain syndrome (CRPS) of the lower extremity. | Significantly longer duration of analgesia in the botulinum toxin group (median time to analgesic failure 71 days (95% CI 12 to 253)) compared with bupivacaine alone (<10 days, 95% CI 0 to 12; P < 0.02). |
| Meier 2009 | 23 patients with lower limb CRPS compared lidocaine delivered intravenously (1% lidocaine; 0.1 ml/kg, maximum 6 ml) with lidocaine sympathetic block (1% lidocaine; 0.1ml/kg, maximum 6ml) in children with lower limb CRPS-I or CRPS-II. In a cross-over trial participants received intravenous (IV) lidocaine and a placebo sympathetic block or a lidocaine sympathetic block and placebo IV. | No significant between-group differences were observed in mean spontaneous pain scores. There were no significant differences between pre- and post intervention spontaneous pain scores for either group. |
| Toshniwal 2012 | Compared continuous SGB (n = 18; 280 ml, 0.125% bupivacaine at 2 mL/hour for seven days) to continuous infraclavicular brachial plexus block (n = 12; 400 ml, 0.125% bupivacaine at 5 mL/hour for seven days) in people with CRPS Type I of the upper extremity. | Significantly lower short-term pain scores in favour of the group receiving the continuous infraclavicular brachial plexus block versus the group receiving the continuous stellate ganglion block. Specifically, at 30 minutes, 2 hours and 12 hours, those receiving the continuous brachial plexus block had significantly lower intensity of pain (0.7, 0.5, and 0.7 respectively) and unpleasantness of pain (0.7, 0.7, and 0.8 respectively) scores |

| | | |
|--|--|--|
| | | compared with those receiving a continuous stellate ganglion block (intensity: 3.3, 2.7, 1.9; unpleasantness: 3, 2.7, 1.9; all $P < 0.05$). |
|--|--|--|

| Study | Methods | Results |
|---|---|--|
| Suprascapular nerve block in hemiplegic shoulder pain (HSP) | | |
| Jeon et al. 2014 | 30 patients with HSP: 10 in SSNB, 10 in intraarticular injection, and 10 in combined. All injections were US-guided. Maximum passive ROM and pain level was assessed | There were significant differences in shoulder ROM with time (1 hour, 1 week, and 1 month after injection). There was no difference according to injection method. Pain was significantly decreased until 1 week after injection. After 1 month pain was relatively increased though remained significantly decreased compared to pre-injection. |
| Adey-Wakeling et al. 2013 | 64 patients with HSP were assigned to the experimental group (SSNB) or placebo group (NS injection). 32 patients were assigned to experimental group and 32 to the placebo group. Primary outcome measure was VAS. Secondary outcome measures were disability and quality of life scales. | Both intervention and control groups demonstrated decreased pain score. Patient that received SSNB demonstrated statistically significant pain reduction compared to control at (1 week, 4 weeks, and 12 weeks). There was no impact on secondary outcome measures. |
| Yasar et al. 2011 | 26 patients with HSP were randomized into intra-articular steroid injections (n=11) and SSNB (n=15). ROM and VAS were measured at baseline, 1 hour, 1 week, and 1 month post injection. | There was significant difference in ROM and pain in both groups. There was no difference between the two groups. |

Participant post-procedure questionnaire (adapted from Zhou et al 2006):

- 
- 0 (No pain) 10 (Worst imaginable pain)

- 0 1 2 3 4 5 6 7 8 9 10

- 
- 0 (No pain) 10 (Worst imaginable pain)

- 
- 0 (No pain) 10 (Worst imaginable pain)

- 
- 0 (No pain) 10 (Worst imaginable pain)

8. On this scale, please mark how much pain you are having **NOW** in your **SHOULDER**,

following the procedure.



9. Assuming that these procedures helped your pain, would you be willing to undergo them again, sometime in the future?
- a. Yes b. No, if not, explain _____

Appendix E

Physician post-procedure questionnaire (adapted from Zhou et al 2006):

List complications:

- ☐ Seizure
- ☐ Coma
- ☐ Cardiac arrest
- ☐ Hypertension, leading to termination of procedure
- ☐ Hypotension, leading to termination of procedure
- ☐ Tachycardia, leading to termination of procedure
- ☐ Bradycardia, leading to termination of procedure
- ☐ Allergic or anaphylactic reactions
- ☐ Unplanned admission to hospital or ICU
- ☐ Technical difficulty (specify)
- ☐ Other (specify)